

lurasidone treatment study. Efficacy over 104 weeks of OL treatment with lurasidone was evaluated for 2 patient groups based on treatment status prior to entering the initial DB study (treatment-naïve [TN] vs. treated previously [TP]). Treatment-naïve was defined as never having received antipsychotic treatment prior to randomization. Efficacy measures included the PANSS total score and the Clinical Global Impressions-Severity (CGI-S) score. Treatment response was defined as  $\geq 20\%$  reduction from baseline in PANSS total score.

**RESULTS:** A total of 50 TN and 221 TP patients completed the 6-week DB study and entered the extension study; and 30 (60.0%) TN and 126 (57.0%) TP patients completed 104 weeks. In the ITT population of the initial DB study, treatment with lurasidone (vs. placebo) yielded larger effects at DB endpoint on the PANSS total score in the TN group (-25.0 vs. -14.4;  $P < 0.02$ ; effect size [ES]=0.75) compared to the TP group (-17.3 vs. -10.0;  $P < 0.001$ ; ES=0.45); and in the CGI-S score in the TN group (-1.07 vs. -0.28;  $P = 0.002$ ; ES=0.97) compared to the TP group (-0.91 vs. -0.55;  $P = 0.005$ ; ES=0.38). During OL treatment with lurasidone, the magnitude of improvement from DB baseline continued to be somewhat larger in the PANSS total score for TN patients ( $n=38$ ) vs. TP patients (151) at week 52 (-32.6 vs. -28.1) and week 104 (-33.6 vs. -29.2); and in the CGI-S score for TN vs. TP patients at week 52 (-2.1 vs. -1.5) and week 104 (-2.1 vs. -1.6). Responder rates during treatment with lurasidone were 72.0% (TN group) and 61.1% (TP group) at OL baseline (number-needed-to-treat [NNT]=10), 100% and 90.1% at week 52 [NNT=11], and 100% and 88.9% at week 104 [NNT=11]. During OL treatment, the most common adverse events for TN vs. TP patients were headache (26.0% vs. 23.5%), nasopharyngitis (24.0% vs. 5.4%), nausea (16.0% vs. 11.8%), and dizziness (16.0% vs. 4.1%).

**CONCLUSION:** In this post-hoc analysis of a 2-year OL extension study, antipsychotic-naïve adolescents with schizophrenia responded well to treatment with lurasidone at doses of 40 mg/day or 80 mg/day. TN patients achieved greater improvement than TP patients during acute treatment; and these greater treatment effects were largely maintained during 2 years of continued treatment with lurasidone.

Funding Acknowledgements: Supported by funding from Sunovion Pharmaceuticals Inc

## 105 Health-Related Quality of Life in Patients with Possible Tardive Dyskinesia Based on Patient and Clinician Assessments

Andrew J. Cutler, MD<sup>1</sup>; Stanley N. Caroff, MD<sup>2</sup>; Huda Shalhoub, PhD<sup>3</sup>; William R. Lenderking, PhD<sup>4</sup>; Ericha Franey, PhD<sup>5</sup>; and Chuck Yonan, PharmD<sup>6</sup>

<sup>1</sup> Clinical Associate Professor of Psychiatry, SUNY Upstate Medical University, Syracuse, NY

<sup>2</sup> Professor, Department of Psychiatry, Perelman School of Medicine and Corporal Michael J. Crescenz Veterans Affairs Medical Center, University of Pennsylvania, Philadelphia, PA

<sup>3</sup> Research Scientist, Patient Centered Research, Evidera, Waltham, MA

<sup>4</sup> Vice President and Executive Director, Patient-Centered Research, Center of Excellence for Outcomes Research, Evidera, Waltham, MA

<sup>5</sup> Manager, Medical Affairs, Neurocrine Biosciences, Inc., San Diego, CA

<sup>6</sup> Senior Director, Neurocrine Biosciences, Inc., San Diego, CA

**ABSTRACT:** Study Objective: Tardive dyskinesia (TD) is a persistent and potentially disabling movement disorder associated with prolonged antipsychotic use. RE KINET, a real-world screening study of antipsychotic-treated outpatients, included patients with movements that were clinician-confirmed as possible TD (Cohort 2) and patients with no involuntary movements (Cohort 1). Baseline data from the patient rated EuroQoL 5-Dimension 5-Level questionnaire (EQ-5D-5L) and Sheehan Disability Scale (SDS) were analyzed to evaluate health related quality of life (Cohort 2 vs. Cohort 1) and the effects of possible TD on quality of life (Cohort 2).

**METHODS:** Assessments included EQ-5D-5L utility score (0=equivalent to death to 1=perfect health); SDS total score (0=no impact to 30=highest impact); patient- and clinician-rated severity of possible TD in 4 body regions (0=none, 1=some, and 2=a lot; summary score, 0 to 8); and patient-rated impact of possible TD in 7 daily activities (0=none, 1=some, and 2=a lot; summary score, 0 to 14). Populations included Cohort 1 (N=450); full Cohort 2 (N=204); and limited Cohort 2 (N=111, patients who self-reported “some” or “a lot” of TD severity in  $\geq 1$  body region). Mean differences between Cohort 2 and Cohort 1 in EQ-5D-5L utility and SDS total scores were analyzed using a generalized linear regression model that was adjusted for potentially confounding factors (e.g., age, sex, psychiatric diagnosis). Associations between TD summary scores (severity, impact) and quality of life (EQ-5D-5L utility, SDS total) were analyzed using a regression model.

**RESULTS:** The mean score difference between full Cohort 2 (N=204) and Cohort 1 (N=450) was significant for EQ-5D-5L utility (-0.037;  $P < 0.05$  [adjusted analysis]) but not SDS total (0.267;  $P > 0.05$ ). However, when limited to Cohort 2 patients who self-reported “a lot” of TD severity ( $n=53$ ) or impact ( $n=33$ ), both EQ 5D 5L utility and SDS total scores were significantly worse than in Cohort 1 ( $P < 0.05$ ). Regression coefficients indicated significant associations between patient-rated impact and

EQ 5D-5L utility in the full Cohort 2 (-0.021,  $P < 0.001$ ) and limited Cohort 2 (-0.024,  $P < 0.001$ ). A significant association was also found with patient rated severity in limited Cohort 2 ( $P < 0.05$ ), but not with clinician-rated severity. Similar results were found for SDS total score.

**CONCLUSIONS:** RE-KINECT patients were consistent in evaluating the severity and impact of TD, whether based on subjective assessments or standardized patient-reported instruments (EQ-5D-5L, SDS). Clinician-rated severity of TD may not always correlate with patient perceptions of the significance of TD. Patient self-assessments (focused on symptom impact) can be clinically relevant; incorporating such measures into everyday practice may provide a more comprehensive approach to TD assessment and management.

Previously presented at APA Annual Meeting, May 2019, San Francisco, CA.

Funding Acknowledgements: Supported by Neurocrine Biosciences, Inc.

## 106

### “Random Twitching” - A Case Presentation

*Andrew Ruege, MD*

Chief Fellow, University of Hawaii, Department of Psychiatry, Honolulu, Hawaii

**ABSTRACT:** Purpose of the study: To present a case about a 12 year old with a movement disorder to educate the community about an uncommon side effect of a commonly utilized class of psychiatric medications. Simple statement of methods: Patient was seen in the context of a consultation-liaison psychiatry capacity during the first author’s general psychiatry residency. Information was obtained from an electronic medical record and interviews with other physicians that treated the patient. Research about the patient’s supposed diagnosis was conducted using a PubMed + OneSearch searches and articles were obtained under the guidance of a certified hospital librarian.

**RESULTS/DISCUSSION:** Withdrawal Emergent Dyskinesia is an uncommon, but debilitating condition that can occur after a rapid discontinuation/dosage change of a neuroleptic. This condition has been documented sparsely in the literature; more literature exists regarding its presence in children than in adults. The condition lasts for 2-3 months and resolves spontaneously in ~90% of cases. The literature that is available suggests (1) avoiding neuroleptic use in children if possible, (2) tapering off antipsychotics slowly, (3) using benzodiazepines and/or beta-blockers to treat symptoms of this condition, and (4) restarting the neuroleptic if symptoms do not improve.

**CONCLUSION:** Withdrawal Emergent Dyskinesia is an uncommon, poorly studied, debilitating condition that can occur after a rapid discontinuation/dosage change of a neuroleptic. Future research efforts could be focused on (a) the prevalence of neuroleptic withdrawal symptoms in both adults and children, (b) the complete neurochemical and neurobiological pathogenesis of WED, and (c) the differences in terms of diagnosis and treatment between dyskinesias associated with both neuroleptic use and/or withdrawal. In addition, the existence of such a condition is yet another reason to reconsider off-label use of neuroleptics to treat behavioral symptoms in the absence of clear psychiatric indications for their use.

## 107

### Examining Real World Treatment Pathways in Parkinson Disease Psychosis: Initial Findings from the INSYTE Observational Study

*Jennifer G. Goldman, MD, MS<sup>1</sup>;*  
*Susan H. Fox, MBChB, PhD, MRCP<sup>2</sup>;*  
*Bruce Coate, MPH<sup>3</sup>; Jesse LoVerme, PhD<sup>4</sup>;*  
*Niccole J. Larsen, PhD<sup>5</sup>; Jeff Trotter, MBA<sup>6</sup>; and*  
*Andrew Shim, PharmD, JD<sup>7</sup>*

<sup>1</sup> Professor, Physical Medicine & Rehabilitation and Neurology, Northwestern University Feinberg School of Medicine and Shirley Ryan AbilityLab, Chicago, IL, USA

<sup>2</sup> Professor, Neurology, Toronto Western Hospital and the University of Toronto, Toronto, ON, Canada

<sup>3</sup> Associate Director, Biostatistics, ACADIA Pharmaceuticals Inc., San Diego, CA, USA

<sup>4</sup> Director, Medical Science Liaisons, Medical Affairs, ACADIA Pharmaceuticals Inc., San Diego, CA, USA

<sup>5</sup> Senior Medical Science Liaison, Medical Affairs, ACADIA Pharmaceuticals Inc., San Diego, CA, USA

<sup>6</sup> President, Worldwide Clinical Trials Inc., Morrisville, NC, USA

<sup>7</sup> Senior Director, Health Economics & Outcomes Research, Medical Affairs, ACADIA Pharmaceuticals Inc., San Diego, CA

**ABSTRACT:** Study Objectives: The INSYTE study provides an understanding of the management of Parkinson disease psychosis (PDP) in actual practice settings, including use of antipsychotic (APs) and their impact on clinical, economic, and humanistic outcomes. Treatment paradigms or the benefits/consequences of various “real world” PDP treatment strategies have not been evaluated. Thus, providers may be using a wide range of AP treatment strategies that contrast with consensus recommendations.

**METHOD:** The INSYTE study is enrolling up to 750 patients from up to 100 sites in the US. Data are compiled at the baseline (BL) visit and from standard-of-care follow up visits over 3 years. PDP treatment pathways are defined